K103023

JUN - 1 2011

510(K) SUMMARY

This 510(k) summary is being submitted in accordance with the Medical Device Amendments of 1976, the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92.

Applicant Name:	Abbott Medical Optics, Inc. 1700 E. St. Andrew Place Santa Ana CA 92705, USA Establishment Registration Number: 2020664
Contact Person:	Evelyn De La Vega Manager, Regulatory Affairs Tel: (714) 247-8487 Fax: (714) 247-8784
Date of Summary Preparation:	March 22, 2011
Device Trade Name:	AMO Irrigation Sleeve
Device Classification:	CDRH Device Class II
Classification Code:	HQC 21 CFR 886.4670 Unit, Phacofragmentation
Reviewing Panel:	Ophthalmic Devices

Devices to Which Substantial Equivalence is Claimed:

510(k) Number	Trade Name	Manufacturer
K844373	Ultra Phaco	OMS*
K840695	Phacoemulsification Kits	Allergan ISP*

*AMO currently owns the rights to these devices.

DEVICE DESCRIPTION

The Abbott Medical Optics (AMO) irrigation sleeve is a device that is intended to direct irrigation solution across the shaft of the phacoemulsification tip, allowing the irrigation solution to enter the eye during ocular surgery. It is a small, molded component that is placed over the phacoemulsification tip. The proposed irrigation sleeve is made of silicone, with a hardness specification of 80+/-5 durometer units. The flow rate of the sleeve is greater than or equal to 18cc, with a length of 0.75 -1.50 inches.

INDICATIONS FOR USE

The proposed irrigation sleeve is a device intended to direct irrigation solution across the shaft of a phacoemulsification tip, allowing the solution to enter the eye during ocular surgery.

STATEMENT OF COMPARISON TO PREDICATE DEVICES

The physical and performance characteristics of the proposed irrigation sleeve are substantially equivalent to those of the predicate devices cleared under K844373, and K840695.

BRIEF SUMMARY OF NONCLINICAL TESTS AND RESULTS

The proposed AMO irrigation sleeve has undergone testing and is in compliance with the following standards; ISO 10993-1:2003 Biological Evaluation of Medical Devices Part 1 Evaluation and Testing, ISO 11137-1:2006 Sterilization of Health Care Product Requirements for Validation and Routine Control- Part 1 Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices, ISO 11137-2:2006 Sterilization of Health Care Product Requirements for Validation and Routine Control- Part 2 Establishing Dose, ISO 11137-3:2006 Sterilization of Health Care Product Requirements for Validation and Routine Control- Part 3 Guidance on Dosimetric Aspects, and ISO 14971:2007 Medical Devices- Application of Risk Management to Medical Devices. Testing of the sleeve included validation of the durometer and tensile strength, flow rate, and product integrity after sterilization. The AMO irrigation sleeve was found to perform equivalently to the predicate irrigation sleeves. Thus, the proposed AMO irrigation sleeve and the predicate devices have similar effectiveness and performance profiles and are considered substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Abbott Medical Optics, Inc.
% Ms. Evelyn De La Vega
Regulatory Affairs Manager
1700 St. Andrew Place
Santa Ana, CA 92705

JUN - 1 2011

Re: K103023
Trade/Device Name: Phacofragmentation Unit
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation System
Regulatory Class: Class II
Product Code: HQC
Dated: May 23, 2011
Received: May 24, 2011

Dear Ms. De La Vega:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Keoia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known):

Device Name: AMO Irrigation Sleeve

Indication for Use:

The irrigation sleeve is a device intended to direct irrigation solution across the shaft of a phacoemulsification tip, allowing the solution to enter the eye during ocular surgery.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K103023